REMARKS

Applicants express gratitude to the Examiner for indicating claims 1-32 as being allowable.

Applicants respectfully request reconsideration and withdrawal of the outstanding Office Action rejections in view of the amendments made in the response filed February 16, 2010 and the following remarks. No new matter has been added.

Response to claim rejections under 35 U.S.C. § 112

Claims 39-47 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that, as amended, claims 39-47 recite that any polypeptide which elicits an immune response to the disease state results in treating the disease state. The Examiner contends that not all immune responses are effective in treating disease states and cites a number of literature references as examples of cases in which immune responses were ineffective in treating disease states. Applicants respectfully disagree.

Applicants submit that the inventive feature of the present invention is the step of administering a bacterial cell which comprises a recombinant nucleic acid molecule encoding a fusion polypeptide that elicits an immune response to the disease state. This bacterial cell has an intracellular persistence in infected cells which makes formerly ineffective treatments with polypeptides that elicit an immune response effective by using the increased pore formation of the bacterial cell to attack infected cells. Further, the specification provides working examples demonstrating that administering this bacterial cell to a mammal to elicit an immune response to a disease state treats the

mammal. Applicants believe that the Examiner is holding "a method for treating a mammal" to too high of a standard, such as preventing or curing the mammal's disease state, whereas, those of ordinary skill would appreciate that the claims are actually directed to a method of treating a mammal by administering such a bacterial cell which increases the effectiveness of polypeptides that elicit an immune response. Clear support for this belief lies in the fact that every drug on the market, e.g., flu vaccine and chickenpox (varicella) vaccine, is ineffective in treating certain patients and certain cases of the disease that the drug is meant to treat. In some cases, very large percentages of patients are treated with drugs that do not cure or prevent their diseases, e.g., 51% effective rate of shingles (herpes zoster) vaccine or 50% effective rate of BCG for tuberculosis, but this does not mean that patients are not treated with these drugs every day.

Moreover, even drugs that are not part of effective treatments *per se*, but that elicit an immune response may still be considered desirable treatments because of the increasing use of adjuvants and other booster factors administered after the initial treatment, e.g., aluminum hydroxide/phosphate formulations, which increase or alter the effectiveness of the elicited immune response. *See, e.g.*, Rerks-Ngarm et al., New England Journal of Medicine, 2009, page 2218, right column, lines 3-7 (enclosed) ("Previous studies have suggested that prime–boost combinations induce qualitative or quantitative protective immune responses that are not seen with either vaccine alone").

Applicants submit that the Examiner has misinterpreted the subject-matter of claim 39, as amended. The subject matter of claim 39 is not directed to a method in which the fusion polypeptide capable of eliciting an immune response is generally

resulting in the treatment of a disease state, but to a method that comprises administering those fusion polypeptides that are capable of eliciting an immune response against a certain disease state. The application provides numerous examples of such polypeptides on page 4, line 25, to page 5, line 33. This passage also discloses what kind of immunogenic response the immunogenic domain should fulfill, i.e., a B cell-mediated immune response or a T cell-mediated immune response. Applicants submit that it is within the common general knowledge of the skilled person to determine whether such an immunogenic response is elicited by the immunogenic domain in question.

Conclusions

In view of the remarks presented herein, as well as the claim amendments made in the response filed February 16, 2010, all of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Early and favorable action is awaited.

Applicant believes that a full and complete reply has been made to the outstanding Office Action and a Notice of Allowance is respectfully solicited.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any fees and to credit any overpayments that may be required with respect to this paper to Counsel's Deposit Account No.02-2135.

Respectfully submitted,

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Enclosure: Rerks-Ngarm, et al. New England Journal of Medicine, 2009

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